

APR 17 2001

Pan Probe Biotech, Inc.

Revision A, February 27, 2001

SUMMARY STATEMENT OF SAFETY AND EFFECTIVENESS

The sponsor, Pan Probe Biotech, Inc., has developed, manufactured, and tested under GMP guidelines, an in vitro diagnostic device for the qualitative testing of urine samples for the presence of cocaine and its metabolites (mainly benzoylecgonine) in a screening format.

The trade name of the device is Pan Probe Biotech LiveSure™ Cocaine Screen Test, having a designated common name of Cocaine Test System and a classification as a Class II device per 21 CFR 862.3250. This device is intended for medical or forensic screening of urines for Cocaine.

The Pan Probe Biotech LiveSure™ Cocaine Screen Tests (i.e., LiveSure™ Cocaine) are rapid in vitro diagnostic qualitative competitive chromatographic immunoassays, in which a chemically labeled drug conjugate competes with any cocaine or its metabolites that may be present in test urinary samples for limited specific antibody binding sites. LiveSure™ Cocaine devices contain a unique membrane that has been pre-coated both with cocaine drug conjugate at the test band, and followed by a built-in reference band with a second antibody as a system control band. A pink colored anti-cocaine monoclonal antibody-colloidal gold conjugate pad is placed on the right side of the test strip. In the absence of cocaine or its metabolites in the test urine, pink colored antibody-colloidal gold conjugate moves chromatographically along with the urinary sample on the membrane by the capillary action. The antibody-colloidal gold conjugate binds to drug conjugate, forming an antibody-antigen complex. This complex binds to drug conjugate as a captured reagent at the test region and produces a visible pink colored band. When cocaine or its metabolites are present in a test urine, that drug or metabolite antigen compete with drug conjugate at the test band region for the limited antibody sites on the antibody-colloidal gold conjugate. When a sufficient concentration of urinary cocaine or its metabolites are present, they block limited antibody binding sites. This blockage binding prevents attachment of pink colored antibody-colloidal gold conjugate to the drug conjugate zone located at the LiveSure™ Cocaine test band region. To serve as a procedural control, a pink colored band in a control region will always appear regardless of presence of cocaine in samples. Negative urine samples produce two pink colored bands, while positive urine samples produce only one pink colored band.

In-house testing of LiveSure™ Cocaine Screen Test Card and Test Strip devices against EMIT® II Assay as a predicate provided data essentially showing equivalency between these devices and the predicate EMIT® II Assay. Additionally, independent clinical testing of 377 urine samples against LiveSure™ Cocaine Screen Test Card and Test Strip devices, as well as EMIT® II Assay at an external reference laboratory resulted in a 100% percent agreement with all GC/MS quantitative positive results. Moreover, LiveSure™ Cocaine Test Card gave a 98.2% agreement and the Test Strip gave a 98.6% agreement with GC/MS negative results, whereas EMIT II® yielded only a 97.5% correlation with GC/MS negatives. In comparing the Test Card and Test Strip positives with EMIT® II positives, a 98.2% and a 97.2% respective agreement with EMIT® II was found. Specificity of Test Card and Test Strip negatives with EMIT® II negatives was shown to be 100%, respectively. In terms of overall accuracy of values at and below the $\pm 25\%$ range of the NIDA/SAMHSA cut-off of 300 ng/ml, however, the LiveSure™ Cocaine Screen Test Card and Strip yielded no false positives or FP, but EMIT® II resulted in 2 FP values for urine samples with GC/MS results below 225 ng/ml. Thus, by comparison, 2 fewer FP by the Test Card and 3 fewer FP by the Test Strip were obtained vs. the predicate EMIT® II Assay results, as judged against the quantitative GC/MS analyses. Finally, the LiveSure™ Cocaine Test Card and the Test Strip gave overall accuracy results of 372/377 (98.7%) and 373/377 (98.9%), respectively, versus GC/MS data, whereas 370/377 (98.1%) accuracy was obtained with EMIT® II. Thus, as judged against GC/MS results from an independent laboratory, the LiveSure™ Cocaine Test Card and Test Strip were determined to be equivalent in performance to each other and somewhat superior in capability versus assays with EMIT® II Cocaine Assay.

Additional information on this submission may be obtained by contacting Alice Yu, Vice President, Pan Probe Biotech, Inc. at: 858-689-9936 - or by fax at 858-689-6896.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 17 2001

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Pan Probe Biotech, Inc.
c/o: James M. Barquest, Ph.D.
California Department of Health Services
Food and Drug Branch
PO Box 942732
601 North Seventh Street (MS 357)
Sacramento, CA 94234-7320

Re: K010967
Trade Name: Pan Probe Biotech LiveSure™ Cocaine Screen Test
Regulatory Class: II
Product Code: DIO
Dated: March 28, 2001
Received: April 2, 2001

Dear Dr. Barquest:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510k Submission for
LiveSure™ COCAINE SCREEN TEST

Pan Probe Biotech, Inc.

Proprietary Information

Revision A, February 27, 2001

510(k) Number (if known): Not yet assigned K010967

Device Name: Pan Probe Biotech LiveSure™ Cocaine Screen Test

INDICATIONS FOR USE STATEMENT:

Pan Probe LiveSure™ Cocaine Screen Tests are diagnostic qualitative lateral flow immuno-chromatographic urinary assays for rapid detection of Cocaine and its metabolites (mainly benzoylecgonine) at the NIDA (National Institute on Drug Abuse) and the SAMHSA (Substance Abuse and Mental Health Services Administration) cut-off level of 300 ng/ml. These tests are designed to give visual, qualitative results and are intended for professional use only. The tests are not intended for quantitative results, nor for over the counter sales.

The tests provide only preliminary analytical data. A more specific alternative method must be used in order to obtain confirmed analytical results. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by NIDA and SAMHSA. Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

P. Bevilacqua (Gorg. Cooper)

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K010967

Prescription Use: ✓
(Per 21 CFR 801.109)

or

Over-the-Counter Use: _____
(Optional Format 1-2-96)